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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,437	12/21/2000	Gregory S. Hamilton	23758	7495

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EXAMINER
STOCKTON, LAURA

ART UNIT	PAPER NUMBER
1626	16

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on February 4, 2003

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 and 63-68 is/are pending in the application.
Of the above, claim(s) 67 and 68 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-3, 5 and 63-66 is/are rejected.
☒ Claim(s) 4 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

09/741,437

PTOL-326 (Rev. 9/96)

★ U.S. GPO: 1996-404-496/40517

DETAILED ACTION

Claims 1-5 and 63-68 are pending in the application.

Election/Restrictions

Newly added claims 67 and 68 are withdrawn as pertaining to a non-elected invention. See the Restriction Requirement dated July 26, 2001 {Paper No. 4} and Applicant's election dated August 22, 2001 {Paper No. 5}.

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations

of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Rejections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case, Applicants are claiming "active truncated derivatives thereof" in claim 5. The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which

compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant specification does not give any guidance or definition as to what is meant by the expression "active truncated derivatives thereof". The instant specification fails to give any guidance as to how the product is made. In order to practice the claimed invention, one skilled in the art would have to speculate Applicant's intention for the expression "active truncated derivatives thereof" found in instant claim 5 and speculate how the product is made. The number of possible "radicals" which could possibly be embraced by the claim would impose undue experimentation on the skilled art worker. Therefore, the expression "active truncated derivatives thereof" is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the expression "active truncated derivatives thereof" found in claim 5. Therefore, the metes and bounds of the claim cannot be ascertained since the instant specification fails to define the expression "active truncated derivatives thereof".

Response to Arguments concerning 112 rejections

Applicant argues that the rejection is improper and should be withdrawn. Specifically, Applicant argues that: (1) the term "active truncated derivatives thereof" is part of a larger phrase, namely, "insulin growth factor"; and (2) the term was not questioned in other patents and cites a few patents).

Applicant's arguments have been considered but have not been found persuasive. The specification should disclose every aspect of Applicant's invention. The instant specification fails to define the expression "active truncated derivatives thereof". Applicant has failed to specify in their remarks where in the instant specification (page and line numbers) the expression "active truncated derivatives thereof" is defined. The instant specification fails to teach how to make "active truncated derivatives thereof". The specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. *In re Gardner*, 166 U.S.P.Q. 138 (C.C.P.A. 1970). The rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by:

A) GB 1,503,244 {for instance, Example 1(A) on page 6}- (claims 3 and 65 anticipated);

B) Lopez Rodriquez et al., WO 96/06846 {for instance, compound 1g on page 7 of the English translation (CA Registry Number 178481-97-5)} – listed on 1449 Form - (claims 65 and 66 are anticipated); and

C) Lopez-Rodriquez, J. Med. Chem., May 23, 1997, Volume 40, pages 1648-1656 {see, for instance, Compound 1a in Table 1 on page 1650} – listed on 1449 Form - (claims 65 and 66 are anticipated).

Each of the above cited references disclose products that are embraced by the instant claims.

Response to Arguments concerning 102(b) rejections

Applicant argues that: (1) a "pharmaceutically acceptable carrier" was never described in GB 1,503,244; and (2) carriers are not necessarily "pharmaceutically acceptable".

In response, GB 1,503,244 does teach carriers (page 17, lines 39-44), such as alcohols, kaolin, talc, etc., that are known in the pharmaceutical art as pharmaceutically acceptable carriers. See also, for example, Jamieson et al., column 3, lines 24-68 and column 4, lines 1-16.

Applicant argues that the rejection of the claims over Lopez Rodriquez et al. {WO 96/06846} and Lopez-Rodriquez {J. Med. Chem., May 23, 1997, Volume 40, pages 1648-1656} is traversed because claim 3, as amended by adding a proviso, circumvents having R represent a piperazine ring.

In response, no such proviso circumventing R representing a piperazine ring is found in newly added claims 65 and 66.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al. {JP 52-083686}, GB 1,503,244, Jamieson et al. {U.S. Pat. 4,230,709} and Lopez Rodriquez {WO 96/06846}, each taken alone or in combination with each other when similar utilities are asserted. English translations of JP 52-083686 and WO 96/06846 have been supplied with the previous Office Action and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims hydantoin products. Wakabayashi et al. (page 3 and Table 1 on pages 9-13), GB 1,503,244 (page 2, Formula I ; Table 1 pages 8-11; and page 17, lines 39-44), Jamieson et al. (column 1, Formula I; column 3, lines 24-68; column 4, lines 1-16; and Example 8 in

column 5) and Lopez Rodriquez (pages 3-4; Example 1g on page 7; page 23, claims 14 and 15) each teach hydantoin products which are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed products.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the products in the prior art and the products instantly claimed is that of generic description.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating central nervous system disorders).

One skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful, for example, in treating central nervous system

disorders. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant invention would have been obvious to one skilled in the art.

Response to Arguments concerning 103 rejections

Applicant argues that the rejection is improper and should be withdrawn. Specifically, Applicant argues that: (1) selecting an embodiment of the claimed invention would not necessarily produce any compound from the generic disclosure of the cited prior art; and (2) the record and explanation in the previous Office Action lack the required motivation and expectation of success.

In response, Applicant is arguing that if a rejection under 35 USC § 102 cannot be made, a rejection under 35 USC § 103 would not be proper. However, this is not the correct criteria for determining an obviousness-type rejection. 35 USC § 103 states, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the

time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

A comparison is made of, for example, the products disclosed in GB 1,503,244 and the third compound listed in instant claim 2. Example 1(A) on page 6 of the GB patent is 3-(3'-trifluorophenylmethyl-phenyl) 1,5-trimethylenehydantoin whereas the third compound listed in instant claim 2 is a (7aS)-2-(4-(trifluoromethyl)phenyl)perhydropyrrolo[1,2-c]imidazole-1,3-dione. The only difference in the two products is the position of the trifluoromethyl group on the phenyl ring (e.g., 3-CF_3 in the GB versus 4-CF_3 instantly claimed). However, the GB teaches (Formula I on page 2) that substitution can be present in any position on the phenyl ring. Note the 4-position substitutions on the phenyl ring in compound numbers 2-7 on page 8 of the GB patent. Therefore, the prior art reference does suggest the instant claimed invention and would motivate one skilled in the art to prepare additional products embraced

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

by the prior art with the expectation of obtaining products that would have, for example, fungicidal activity.

For all the reasons given above, the rejection is proper and maintained.

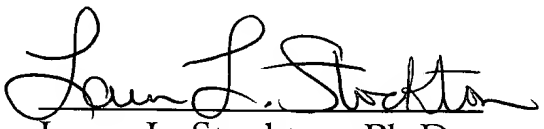
Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



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Art Unit 1626, Group 1620
Technology Center 1600

April 24, 2003